

BD Medical - Pharmaceutical Systems
920 East 19th Street
Columbus, NE 68601
tel: 402.564.3181
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Certified Mail Receipt: 7015 3430 0000 5373 9888

July 19, 2019

Mr. Kevin Stoner
Air Quality Division, NDEQ
PO Box 98922
Lincoln, NE 68509-8922

RE: NESHAP Summary Report
1st Half CY 2019
BD Pharmaceutical Systems
IIS #73007

Dear Mr. Stoner:

As required by 40 CFR Part 63, Subpart O, we are submitting a NESHAP summary report for the operation of our ethylene oxide (EO) sterilizer, for the time period January 01, 2019 through June 30, 2019. The report is used to summarize the continuous monitoring system (CMS) performance.

We had no excess emissions during the reporting period. Our sterilizer system is designed so that any emissions normally directed to the catalyst would be diverted to an intermediate balancer tank that stores EO if the catalyst is bypassed for any reason. Therefore, although we have had startup and shutdown events as well as regularly scheduled shutdown time for maintenance and calibration as recorded in our data collection system, these have not resulted in excess emissions and the attached summary sheet indicates zero excess emissions.

The critical operating parameter for the catalytic oxidizing unit (Lesni) is the catalyst bed operating temperature of 150 degrees C, based on the manufacturer's recommended minimum operating temperature. The control system continuously monitors the bed temperatures and shuts down the oxidizer and sterilization processes when the bed temperature falls below 150 degrees C. A strip chart recorder records the average daily oxidation temperature, and these charts are maintained on file. As noted in the enclosed summary report, there were no operating parameter deviations during the reporting period.

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Because the total duration of control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period the full excess emissions and CMS performance report do not need to be submitted as per 63.10(e)(3)(vii). Therefore, only the summary report is being submitted.

If you have any questions, please call me at 402-563-8715.

Thank you.

A handwritten signature in black ink, appearing to read "Jaime Petersen", with a large, looping flourish at the end.

Jaime Petersen BSN RN COHN
EHS Leader

NESHAP Summary Report

Summary Report - Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance

IIS-73007

Becton Dickinson Pharmaceutical Systems
920 E. 19th St.
Columbus, NE 68601

Reporting period:

From: 01/01/2019 To: 06/30/2019

Operating parameter limit: 150°C minimum catalyst bed temperature

Air pollutant regulated: Ethylene oxide

Date of last CMS certification or audit 3/25/2019

Process units: Double-ended Ethylene Oxide
Sterilization Chamber

Manufacturer/Model # of Monitored equipment Geringe: GEE2923118-AR2 EX
Sterilizer - project #17020

Total operating time 4331.27 hours

Emission data summary:

Total deviation duration 0.0 hours

Total deviation duration (% of operating time) 0.00%

Duration of each deviation type

Startup 0 hours

Shutdown 0 hours

Control equipment problem 0.0 hours

Process problem 0 hours

Other 0.0 hours

CMS performance summary

Total CMS downtime 0 hours

Duration of downtime (% of operating time) 0%

Duration of each deviation type:

Monitoring equipment malfunction 0 hours

Other equipment malfunction 0 hours

QA control calibration 0 hours

Other 0 hours

Changes to CMS, processes or controls since last report None

Stack test conducted on 07/11/2018

Signed: William P. Campbell, Dir. of Plant Operations

Date:

24 JUL 19